

Exhibit 9

https://dilincentral.dcri.duke.edu/causality/edu/duke/dcri/dilincCausality/view/cases/caseDetails/case-details.jsf?_afPfm=-2b1eca2 [13-Oct-15 16:28:09]



Initial Clinical Narrative Prospective Study

Personal
Information



	Month	Day	Year
Date Completed:	12	14	2013
Patient ID No:			-0242
Age: 30	Gender: female		
Completed by:	RJF		

Implicated Drug(s) or Dietary Supplement(s): List in order of likely implication	Start Date mm/dd/yy	Stop Date mm/dd/yy	Exposure time in Days
1. (Drug or CAM) Oxyelite Pro Indication: weight loss	04/Un/2013	6/14/13	60
2. (Drug or CAM) Indication:			
3. (Drug or CAM) Indication:			
Onset of qualifying labs 6_/_15_/_2013		Onset of symptoms _06_/_12/_2013	

	No	Yes/ Specify or date?
Underlying chronic liver disease?	no	
Hospitalized?	Yes	6/15 to 6/22/13
Liver Transplant?	No	
Liver biopsy?	Yes	6/19/13
Death?	No	
Drug allergies?	No	
Alcohol use?	Yes	Occasional

Relevant PMH	
Relevant Conns	BCP,

Provide a brief summary of presentation and rational for ascribing the event as DILI (relevant information)

A 30 y.o. Korean- American F previously took oxyelite which contains multiple herbs and caffeine in an effort to control her weight from July 2010 to April 2012. Patient then became pregnant and delivered by c-section in December 2012. Pt resumed taking the product in April 2013 to June 14th 2013. She had also been started on a combination BCP of levonorgestrel/ ethinyl estradiol in early May 2013. Patient developed new onset pruritis and darkening of her urine that led to hospitalization on 6/15/13; no fever or rash. Assessment for hepatitis A, B, C, and autoimmune markers were negative. In addition, testing for CMV and EBV was negative as well as liver imaging. Initial AST was 710, ALT 1972, alk phos of 58 and bilirubin of 3.8 mg/dl. A liver biopsy on 6/19/13 demonstrated prominent lobular hepatitis with multifocal hepatocyte injury and prominent sinusoidal inflammation. At baseline DILIN visit in hospital on 6/21/13 AST was 725, ALT 2039 and bilirubin was 7.7. Patient was treated with cholestyramine and anti-histamines and discharged home. At 6 month DILIN visit on 11/12/13, patient felt much improved and had normal LFT's as of July 30th, 2013.